

**IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION**

Kathryn Kiker, et al.,	:	
	:	
Plaintiffs,	:	
	:	Case No. 2:14-cv-02164-EAS-TPK
vs.	:	
	:	
SmithKline Beecham Corporation d/b/a	:	Chief Judge Edmund A. Sargus Jr.
GlaxoSmithKline LLC,	:	Magistrate Judge Terence P. Kemp
	:	
Defendant.	:	
	:	

**DEFENDANT GLAXOSMITHKLINE LLC’S
MOTION *IN LIMINE* TO EXCLUDE EVIDENCE
OF GSK MARKETING AND PROMOTION UNRELATED TO
PLAINTIFF KATHRYN KIKER OR HER PRESCRIBING DOCTOR
(ORAL ARGUMENT REQUESTED)**

Defendant GlaxoSmithKline LLC (“GSK”) submits its Motion *in Limine* to Exclude Evidence of GSK Marketing and Promotion Unrelated to Plaintiff Kathryn Kiker or Her Prescribing Doctor.

I. INTRODUCTION

There are two primary issues in this product liability case: (1) whether Kathryn Kiker’s alleged use of the prescription antidepressant Paxil® (“Paxil”) during the first trimester of her pregnancy in 2000 caused C.S. to develop a ventricular septal defect (“VSD”); and (2) whether Paxil’s labeling about use in pregnancy was adequate when Dr. Julie Guthrie prescribed Paxil to Ms. Kiker in 2000.

GSK anticipates that Plaintiffs will attempt to stray far afield from these core issues by attempting to introduce evidence of GSK’s marketing and promotional materials, internal communications, and other documents that are unrelated to either Ms. Kiker or her Paxil

prescribing physician Dr. Guthrie, including: (1) marketing and promotional materials that were never implemented, or were not seen or relied upon by Ms. Kiker or Dr. Guthrie; and (2) testimony and call notes from sales representatives unrelated to Dr. Guthrie. Because such materials have no connection to the facts of this case, they are irrelevant and, in many instances, prejudicial to GSK; any testimony or evidence regarding them should be excluded under Federal Rules of Evidence 401, 402, and 403.

II. ARGUMENT & CITATION OF AUTHORITY

A. There Is No Evidence that Either Dr. Guthrie Or Ms. Kiker Relied Upon Any Advertisements, Promotional Materials, Or Statements by Sales Representatives in Deciding to Prescribe Or to Take Paxil.

There is no competent evidence in the record that Dr. Julie Guthrie, the doctor who prescribed Paxil to Ms. Kiker during her pregnancy with C.S., relied on any GSK advertisements, promotional materials, or statements by GSK sales representatives when prescribing Paxil to Ms. Kiker. Instead, Dr. Guthrie's deposition reveals that:

- Dr. Guthrie does not remember any of the GSK sales representatives who called on her regarding Paxil, (*see* Aug. 10, 2015 Dep. of Julie A. Guthrie ("Guthrie Dep.") at 43-45 (relevant excerpt attached as Ex. 1));¹
- Dr. Guthrie does not recall any conversation about Paxil with any GSK sales representative at any point in time, (*id.* at 135);
- Dr. Guthrie has no specific recollection of any GSK representative at all, (*id.* at 136);
- Dr. Guthrie does not recall attending any CME, speaker program, or other event in which speakers discussed the use of Paxil during pregnancy, (*id.*);
- During her deposition, Dr. Guthrie was not *shown* a single GSK promotional piece, advertisement, internal communication, or any other sales or marketing document;

¹ For the Court's convenience, exhibits are attached to the Declaration of William D. Kloss, Jr., accompanying this Motion.

- During her deposition, Dr. Guthrie was not *asked a single question* about any GSK promotional piece, advertisement, internal communication, or any other sales or marketing document; and
- Dr. Guthrie wrote prescriptions for Paxil based on her own judgment and medical acumen, not on anything that a GSK sales representative told her. (*Id.*)

Consequently, there is no evidence in this case that any of GSK's sales or marketing statements have anything to do with Dr. Guthrie's decision to prescribe Paxil to Ms. Kiker.

Similarly, there is no evidence that Ms. Kiker relied on any sales or marketing statements in deciding to take or continue taking Paxil during her pregnancy with C.S. When asked if she had ever seen an advertisement for Paxil, Ms. Kiker said, "I believe I saw possibly one in a magazine." (Aug. 20, 2015 Dep. of Kathryn L. Kiker ("Kiker Dep.") at 15 (relevant excerpts attached as Ex. 2).) When pressed to give any further details about the "one" advertisement that she believes she "possibly" saw, however, Ms. Kiker admitted the following:

- She could not recall any of the content, pictures, or anything else about the magazine advertisement, (*id.* at 15-16);
- She could not remember the name of the magazine or type of magazine in which she saw the advertisement, (*id.* at 15);
- She could not recall whether she saw the magazine advertisement just once or on multiple occasions, (*id.* at 16);
- She could not recall whether she saw the magazine advertisement before or after she started taking Paxil, (*id.*); and
- Most importantly, this one magazine advertisement ***did not have any impact*** on whether Ms. Kiker decided to take or continued to take Paxil. (*Id.*)

Further, Ms. Kiker testified that she has not seen any other Paxil advertisement or promotion other than this one magazine advertisement, (*id.* at 16-17); she has never visited any GSK website, (*id.* at 180); she has never conversed with any employees of GSK, including sales representatives, (*id.* at 180-81); and she first heard about Paxil from one of her doctors. (*Id.* at

41.) Consequently, just as there is no evidence that any Paxil sales or marketing communications played any part in Dr. Guthrie's decision to prescribe Paxil to Ms. Kiker, there also is no evidence that any such communications influenced Ms. Kiker's decision to take Paxil.

B. Marketing Or Promotional Materials that Were Not Seen Or Relied Upon Are Inadmissible.

Given the absence of any evidence connecting GSK's promotion of Paxil to either Dr. Guthrie or Ms. Kiker, any alleged promotion concerning the use of Paxil during pregnancy has no relevance to this case and should be excluded. *See* FED. R. EVID. 401 (evidence is relevant if it has any tendency to make a fact more or less probable than it would be without the evidence); *See Koloda v. General Motors Parts Div., General Motors Corp.*, 716 F.2d 373, 375 (6th Cir. 1983) ("Relevancy is the threshold determination in any decision regarding the admissibility of evidence; if evidence is not relevant, it is not admissible."). This applies not only to promotional materials never seen or relied upon by Dr. Guthrie or Ms. Kiker, but also to any internal communications or documents regarding the creation or distribution of such materials.

Other federal courts have agreed that absent evidence that a prescribing physician was exposed to promotional and advertising materials, such evidence is not relevant. *See In re Wright Med. Tech. Inc.*, 2015 U.S. Dist. LEXIS 147805, at *42–44 (N.D. Ga. Oct. 30, 2015) ("Plaintiff is not entitled to present evidence or testimony concerning marketing materials that were not reviewed or relied upon by [plaintiff's physician]."); *Skibniewski v. Am. Home Prods. Corp.*, 2004 U.S. Dist. LEXIS 31014, at *3, *30 (W.D. Mo. Apr. 1, 2004) (excluding evidence of defendant's publications and marketing campaigns where nothing in the record established that the plaintiff or her physician relied on or were influenced by such publications or marketing campaigns); *In re Norplant Contraceptive Prods. Liab. Litig.*, 1997 WL 81092, at *1 (E.D. Tex.

Feb. 21, 1997) (“Absent evidence that the physicians were exposed to the . . . materials, the court finds that the promotional and advertising materials are not relevant evidence.”).

More specifically, in the context of another Paxil pregnancy case with allegations similar to those in this case, a Pennsylvania court granted GSK’s motion *in limine* to exclude evidence of GSK marketing and promotion unrelated to the plaintiff mother or her prescribing physician, including but not limited to the following categories:

- GSK’s direct-to-consumer advertising;
- Internal GSK marketing budgets, sales projections, and marketing research, including the marketing efforts reflected in these documents;
- GSK’s sales training materials;
- “Field mail” sent to GSK sales representatives;
- GSK’s Speakers’ Bureau for Paxil;
- Promotional materials for Paxil, except the FDA-approved prescribing information;
- Materials from a program entitled “The Hidden Diagnosis: Uncovering Anxiety and Depressive Disorders” and other GSK-sponsored educational programs;
- Notes from meetings between GSK representatives and medical providers who were not involved in the plaintiff’s treatment;
- Draft manuscripts that reference use of antidepressants or Paxil/paroxetine during pregnancy;
- Alleged “ghostwriting” by GSK or scientific articles;
- Other materials not viewed by the prescribing physician but offered allegedly to prove that GSK improperly over-promoted Paxil; and
- Any other materials relating to Paxil not yet created and distributed before the prescribing physician prescribed Paxil to plaintiff during the pregnancy at issue.

(See *Blyth v. GSK*, Case No. 3305 (Phila. Ct. Com. Pl.) Nov. 9, 2010 Order at Control No.

10030243 No. 22 (granting Subpart 3 of GSK’s Omnibus Motion *in Limine*) (attached as Ex. 3).)

GSK respectfully requests that this Court similarly exclude evidence of GSK marketing and promotion unrelated to Dr. Guthrie and Ms. Kiker, including but not limited to evidence from the above categories and any marketing or promotional materials relating to Paxil as a Pregnancy Category B medication.²

Similarly, this Court should exclude as irrelevant any reference to the Case Study Publication for Peer Review program (known as “CASPPER”), a short-lived GSK program designed to facilitate the publication of case studies by physicians in peer-reviewed scientific journals. In its two years of existence, there were perhaps five published items that possibly may have been connected with the Paxil CASPPER program. None of these publications relates to the use of Paxil in pregnancy or by women of child-bearing age. (*See* Table of CASPPER Publications (attached as Ex. 4).) Importantly, there is no evidence at all that Dr. Guthrie ever read or was aware of any publication potentially arising from the CASPPER program, let alone that such a publication had any effect on Dr. Guthrie’s decision to prescribe Paxil to Ms. Kiker. As such, evidence of the CASPPER program is wholly irrelevant.³

These arguments apply with even greater force to proposed marketing efforts related to Paxil that GSK *never actually implemented*. For instance:

² Consistent with this Court’s prior ruling, evidence of or reference to marketing or promotional materials that concern when Paxil was a Pregnancy Category B medication (December 1992 – May 1996) is irrelevant in this case because Paxil had already been a Pregnancy Category C medication for many years by the time Ms. Kiker was prescribed Paxil during her pregnancy with C.S. in 2000. (*See* Dec. 15, 2016 Opinion and Order (Doc. 151) at 29 (“Plaintiffs have not demonstrated that this testimony [regarding the Category B labeling] ‘fits’ the issues in this case, inasmuch as the drug was listed as Category C at the time it was prescribed to Ms. Kiker.”).) Additionally, there is no evidence from Dr. Guthrie that she based her decision to prescribe Paxil to Ms. Kiker (much less to any other female patient) on anything remotely related to Paxil marketing or promotional activities by GSK that occurred when Paxil was a Pregnancy Category B medication. During her deposition noticed by Plaintiffs, Dr. Guthrie was never shown or asked about promotional materials from that period; about the Pregnancy Category B label for Paxil; or about what effect, if any, the Pregnancy Category B language might have had on her prescribing decision.

³ Other Paxil pregnancy courts have excluded evidence related to CASPPER. (*See Rader v. GSK*, Case No. 3672 (Phila. Ct. Com. Pl.) Mar. 14, 2016 Order (granting Subpart 3 of GSK’s Omnibus Motion *in Limine*) (attached as Ex. 5); *Adams v. GSK*, Case No. 3604 (Phila. Ct. Com. Pl.) July 10, 2012 Order (granting Subpart 4 of GSK’s Omnibus Motion *in Limine*) (attached as Ex. 6); Ex. 3, *Blyth v. GSK* Nov. 9, 2010 Order (granting Subpart 4 of GSK’s Omnibus Motion *in Limine*).)

- The “Mother Knows Best” proposed advertising campaign that was submitted to GSK by a third-party advertising agency in 1999 but was never implemented and for which no marketing materials were ever created, (*see* Aug. 14, 2008 Dep. of Barry Brand in *Hayes v. GSK*, Case No. 07CV-682CVE SAJ (N.D. Okla.) at 189:12-190:14 (relevant excerpts attached as Ex. 7); Aug. 28, 2008 Dep. of Bonnie Rossello in *Steele v. GSK*, Case No. 37373 (Dist. Ct. Brazoria Cty., Tex.) at 261:18-22 (relevant excerpt attached as Ex. 8));
- A video created in or around 1999 in which the Paxil marketing team portray themselves as members of the military. The video was not shown to any sales representatives or healthcare providers, (Bonnie Rossello Decl. ¶¶ 3-5 (attached as Ex. 9));
- Documents referencing GSK’s sponsorship of the website BabyCenter.com and a 2002 email about a “potential Paxil opportunity” to advertise on that website.⁴ There is no evidence that GSK ever advertised Paxil on BabyCenter.com, (*see* July 6 and 7, 2009 Dep. of David Pernock in *In re: Paxil Pregnancy Cases*, Case No. 3220 (Phila. Ct. Com. Pl.) at 907-09 (relevant excerpt attached as Ex. 10));
- A February 23, 1998 memorandum from public relations firm Ruder Finn that discusses the impending release of a scientific study about pregnancy outcomes following maternal use of certain selective serotonin reuptake inhibitors (“SSRIs”) (like Paxil) and proposing that the agency create a “b-roll”⁵ of video images of pregnant women, new mothers, statistics of women and depression, and Paxil manufacturing footage to provide to broadcast outlets to play while reporting on the study. (*See* Exhibit 311 on Plaintiffs’ Exhibit List (Doc. 159).) No b-roll on the topic of Paxil and pregnant women was released at any time during 1998, (*see* Richard Kellner Decl. ¶¶ 3-4 (attached as Ex. 11)); and
- Draft manuscripts that discuss the use of SSRIs (including Paxil) by women of childbearing age, including use during pregnancy or breast feeding, but were never finalized or published. (*See* Mary Anne Knewstub Decl. ¶¶ 4-7 (detailing GSK’s efforts to find published versions of certain draft manuscripts) (attached as Ex. 12).)

Because these marketing efforts were never implemented, neither Ms. Kiker nor Dr. Guthrie could have relied upon them and, therefore, they have no relevance to this case.⁶

⁴ The 2002 email is also irrelevant because it is from after C.S. was born. (*See* GSK’s Mot. in *Limine* to Exclude Evidence of GSK’s Knowledge, Conduct, or Communications After October 22, 2000.)

⁵ B-roll footage is video footage, often without a narration sound track, used by broadcasters to supplement the main elements of a news story. A broadcaster chooses select portions of the b-roll video and airs them while providing her own voice-over.

⁶ Previous courts that have considered the specific unimplemented marketing materials listed here have excluded them. (*See* Ex. 5, *Rader v. GSK* Mar. 14, 2016 Order (granting Subpart 1 of GSK’s Omnibus Motion in *Limine*); Ex. 6, *Adams v. GSK* July 10, 2012 Order (granting Subpart 1 of GSK’s Omnibus Motion in *Limine*); Ex. 3, *Blyth v. GSK* Nov. 9, 2010 Order at Control No. 10030243 No. 22 (granting Subpart 2 of GSK’s Omnibus Motion in *Limine*); *Kilker v. GSK*, Case No. 1813 (Phila. Ct. Com. Pl.) Mot. Hr’g Tr., Sept. 3, 2009 at 80-84 (relevant excerpt attached as Ex. 13).)

Even assuming that the foregoing materials had some probative value — which they clearly do not — any such marketing or promotional materials should nevertheless be excluded because they are unfairly prejudicial, would confuse the jury, and would result in a waste of time.⁷ See FED. R. EVID. 403 (evidence may be excluded “if its probative value is substantially outweighed by a danger of ... unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence”); *United States v. Vance*, 871 F.2d 572, 576 (6th Cir. 1989). If these materials were admitted, GSK would be forced to defend itself by explaining each of the marketing and promotional documents, the circumstances that produced them, and whether Ms. Kiker and Dr. Guthrie ever viewed them. This would have the effect of creating several, lengthy, collateral trials-within-a-trial, which would undoubtedly divert the jury’s attention from the core issues of the case. At the end of all this extraneous evidence, the jury would be no further along in deciding the heart of the case — namely, whether Paxil caused C.S.’s VSD and the adequacy of the then-current Paxil labeling about its use in pregnancy. Because such marketing and promotional evidence would unnecessarily prolong the trial of this case and because it would hamper, not help, the jury in its work, it should be excluded.

C. Testimony And Call Notes from GSK Sales Representatives with No Connection to Dr. Guthrie, Including But Not Limited to Brad Anderson And Tracy Lepper, Are Inadmissible.

Under the same reasoning, the Court should exclude testimony and call notes from GSK sales representatives who never even called upon Dr. Guthrie. Plaintiffs have designated deposition testimony from two sales representatives taken in other Paxil pregnancy cases who

⁷ Plaintiffs have designated a substantial amount of deposition testimony of William Collier, who was deposed solely on the topic of Paxil marketing for pediatric or adolescent use. (Pls.’ Deposition Designations (Doc. 158) at 23-30.) Because Ms. Kiker was an adult at all times when she was prescribed and ingested Paxil, any testimony or evidence related to Paxil marketing for pediatric or adolescent use should similarly be excluded as irrelevant and unduly prejudicial to GSK.

never called upon *any* healthcare providers in Ohio, let alone Ms. Kiker's prescribing doctor. Specifically, Plaintiffs have designated testimony from Brad Anderson (a sales representative from Idaho) and Tracy Lepper (a sales representative from Washington state). (*See* Plaintiffs' Deposition Designations (Doc. 158) at 10-12, 43.) Similarly, Plaintiffs may seek to introduce "call notes," *i.e.*, summaries of visits with doctors that were written by GSK sales representatives, that pertain to doctors other than Dr. Guthrie, who treated Ms. Kiker.

Other courts have held that such evidence is inadmissible as irrelevant and unduly prejudicial. (*See* Ex. 5, *Rader v. GSK*, Mar. 14, 2016 Order (granting Subpart 5 of GSK's Omnibus Motion *in Limine*); Ex. 6, *Adams v. GSK*, July 10, 2012 Order (granting Subpart 5 of GSK's Omnibus Motion *in Limine*); Ex. 3, *Blyth v. GSK*, Nov. 9, 2010 Order at Control No. 10030243 No. 22 (granting Subpart 7 of GSK's Omnibus Motion *in Limine*).)

When Dr. Guthrie prescribed Paxil to Ms. Kiker, she did not rely upon *any* information from any GSK sales representatives – not the sales representatives who called on her and certainly not the sales representatives who called on other doctors in distant parts of the country. Instead, Dr. Guthrie does not recall *any* conversation about Paxil with *any* GSK sales representative at any point in time; in fact, she has no specific recollection of any GSK representative at all. (Ex. 1, Guthrie Dep. at 135-36.) When Dr. Guthrie wrote prescriptions for Paxil, she did so based on her own judgment and medical acumen, not based on anything that a GSK sales representative told her. (*Id.* at 136.)

Consequently, *any* evidence of sales representative communications or training should be excluded as irrelevant because that evidence cannot bear upon Dr. Guthrie's prescribing decision. That is unquestionably true of sales representative communications that Dr. Guthrie

never heard or saw and those involving sales representatives whom she has never met. *See In re Norplant Contraceptive Prods.*, 1997 WL 81092, at *1.

Even if there were arguably some minimal probative value of this testimony or these call notes (which is not the case), it would be substantially outweighed by the risk of unfairly prejudicing GSK, confusing the jury, and causing undue delay. *See* FED. R. EVID. 403. For example, if the Court were to allow Plaintiffs to present evidence from Mr. Anderson or Ms. Lepper, GSK would be required to counter-designate with the testimony of other GSK sales representatives to show that Mr. Anderson and Ms. Lepper are outliers. This would lead to a mini-trial of GSK sales representatives, none of whom actually called on Dr. Guthrie. Moreover, using Mr. Anderson's or Ms. Lepper's testimony, or that of any other GSK sales representative, would be particularly confusing to the jury here because Plaintiffs failed to depose the sales representatives who actually did call upon Dr. Guthrie. Thus, allowing Plaintiffs to introduce testimony or call notes from sales calls on doctors who never treated Ms. Kiker would only mislead and confuse the jury into thinking those calls were made on Dr. Guthrie, which would be untrue. For these reasons, GSK respectfully asks the Court to exclude any deposition testimony of GSK sales representatives that did not call on Ms. Kiker's Paxil prescribing physician, Dr. Guthrie. *See* FED. R. EVID. 403.

III. CONCLUSION

For the foregoing reasons, GSK respectfully requests that this Court grant its Motion *in Limine* and enter an order excluding evidence of GSK's marketing and promotion unrelated to Plaintiff Kathryn Kiker or her prescribing doctor, including (1) marketing and promotional materials not seen or relied upon by Ms. Kiker or Dr. Guthrie; and (2) testimony from and evidence regarding GSK sales representatives who never even called upon Dr. Guthrie.

/s/ William D. Kloss, Jr.

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CERTIFICATE OF SERVICE

This is to certify that a copy of the foregoing was served upon all counsel of record, this
24th day of January, 2017, by the Court's electronic service.

/s/ William D. Kloss, Jr.

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GlaxoSmithKline LLC,	:	Magistrate Judge Terence P. Kemp
	:	
Defendant.	:	
	:	

ORDER

AND NOW, this ____ day of _____, 2017, upon consideration of the Motion *in Limine* No. to Exclude Evidence of GSK's Marketing And Promotion Unrelated to Plaintiff Kathryn Kiker Or Her Prescribing Doctor filed by Defendant GlaxoSmithKline LLC, and any response or reply thereto, and having considered the arguments of counsel, it is hereby ORDERED that Defendant's Motion is GRANTED.

Date

Edmund A. Sargus, Jr.
Chief United States District Judge